ABSTRACT

VALIDATION OF THIN LAYER CHROMATOGRAPHY-DENSITOMETRY FOR ANALYSIS OF SILDENAFIL CITRATE IN MEN'S HEALTH SUPPLEMENTS STAMINA

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Sildenafil citrate is a chemical drug which is forbidden by National Agency of Food and Drug Control (BPOM) to be added into men's health supplements stamina. Recently, some men's health supplements stamina had been found containing sildenafil citrate by BPOM. The aim of this study is to validate a TLC-Densitometry method used in the quantitative analysis of sildenafil citrate. Validation of the method that were determined i.e., selectiviy, detection limit, quantitation limit, linearity, accuracy and precision. A good solvent for extracting sildenafil citrate from matrix sample is methanol. Sildenafil citrate was separated from matrix's component on silica gel F 254 using MeOH-EA (1:2) v/v as eluent. Retardation factor (Rf) of sildenafil citrate was 0.41, resolution factor between sildenafil citrate and the nearest matrix compound was 3.0. Sildenafil citrate spectrum showed maximum wavelength at 304 nm. The respond was to be linear at the range of sildenafil citrate concentration 500-1500 ppm. Linearity test results given linear correlation 0.9989 and Vxo 2.02% . The result showed that the detection limit of sildenafil citrate was 4.96 and quantitation limit was 15.03 ppm. Recovery of sildenafil citrate were found 98.46-101.09% with average of 99.83% and the precision result was 0.99%. Therefore, this method can be used for quantitative analysis of sildenafil citrate as the parameters of validation has meet the requirement.

Keywords : Sildenafil Citrate, TLC-Densitometry, validation method